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10/042,818	01/09/2002	Mark Lemko	FLI-10502/03	7313

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Ronald W. Citkowski
Gifford, Krass, Groh, Sprinkle
Anderson & Citkowski, P.C.
280 N. Old Woodward Ave. Suite 400
Birmingham, MI 48009

EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	3

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/042,818	Applicant(s) Mark
	Examiner Gollamudi Kishore	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-23* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *2*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. **The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:**

> **A person shall be entitled to a patent unless -**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

2. **Claims 1, 3, 7, 12, 13, 15, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hara (4,686,211).**

Hara discloses compositions containing 2 % lidocaine and 8 % arginine salt for external applications (Example 6 on col. 6).

Claim Rejections - 35 USC § 103

3. **The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

4. **Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hara cited above.**

Hara's teachings have been discussed above. What is lacking Hara are the teachings of the use of instant amounts of lidocaine or arginine. However, since these are composition claims and varying the amounts of the components in a composition is deemed obvious to one of ordinary skill in the art to obtain the best possible results.

5. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hara cited above, further in view of Mezei (4,937,078).

Hara's teachings have been discussed above. What is lacking Hara are the teachings of the use of liposomes as carriers for lidocaine.

Mezei while disclosing topical compositions teaches that liposome encapsulated local anesthetics when applied to skin or mucous membranes provided greater anesthesia than the same agents incorporated in conventional vehicles (note the abstract and claim 8).

The use of liposomes for encapsulating lidocaine in the compositions of Hara would have been obvious to one of ordinary skill in the art since such an incorporation would provide greater anesthesia than the same agents incorporated in conventional vehicles as taught by Mezei.

6. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parks (6,391,869)

Parks discloses compositions for the treatment of anorectal disorders. The compositions contain a first active ingredient which is a NO donor which include L-arginine or nitroglycerine and additional active ingredients such as local anesthetics such

as lidocaine and antiinflammatory agents such as naproxen (note col. 9, line 16 et seq., col. 10, lines 8-13, col. 16, lines 33-44; col.18, lines 15-27; col. 22, lines 18-42; col. 23, lines 13-32; Examples and claims). The compositions could be in liposomal form (col. 17, line 44; col. 22, line 13). The amount of the NO donor according to Parks is 0.01 to 10 % (col. 10, lines 39-40). What is lacking in Parks is the teachings of the amounts of the anesthetic. However, it is deemed obvious to one of ordinary skill in the art to vary the amounts of the active ingredients with the expectation of obtaining the best possible results.

7. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fogel (6,159,944) in combination with Parks (6,391,869) cited above.

Fogel discloses compositions for treating painful conditions of the anal regions such as hemorrhoids. The compositions contain a combination of nitroglycerin (NO donor) and lidocaine (note the abstract and the claims).

What is lacking in Fogel is the teaching of the use of arginine.

Parks as discussed above, while disclosing compositions for the treatment of anorectal disorders teaches that the use of NO donors is a promising approach to treat anal disorders. The NO donors include nitroglycerin and arginine (note col. 9, line 16 et seq.).

The use of arginine instead of nitroglycerin in the compositions of Fogel would have been obvious to one of ordinary skill in the art because of the equivalency in terms of the treatment of the same condition disclosed by Parks.

8. Claims 2, 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parks, OR Fogel (6,159,944) in combination with Parks (6,391,869) as set forth above, further in view of Mezei cited above.

The teachings of Parks and Fogel have been discussed above. Although Parks suggests the use of liposomes for the delivery of the active ingredients, he does not provide a specific reasoning.

Mezei as pointed out above, while disclosing topical compositions teaches that liposome encapsulated local anesthetics when applied to skin or mucous membranes provided greater anesthesia than the same agents incorporated in conventional vehicles (note the abstract and claim 8).

The use of liposomes for encapsulating lidocaine in the compositions of Hara would have been obvious to one of ordinary skill in the art since such an incorporation would provide greater anesthesia than the same agents incorporated in conventional vehicles as taught by Mezei.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

July 9, 2003